REMARKS

Reconsideration of this application, as amended, is respectfully requested. The specification has been amended to insert SEQ ID numbers for the sequences shown in Figures 12 and 13. Claims 47-50 have been cancelled. Claims 38, 39 and 47 have been amended. With this amendment, claims 38-47 are pending in this application. These amendments are made without prejudice or disclaimer, do not add new matter, and are supported by the originally filed specification. Consideration and entry of these amendments is respectfully requested. Applicants reserve the right to prosecute any amended, cancelled, or otherwise unclaimed subject matter in this or another application.

SEQUENCE LISTING

The sequence listing submitted on May 7, 2007 includes SEQ ID NOS. 11 and 12 which correspond to the sequences of Figure 12, and SEQ ID NOS. 13 and 14 which correspond to the sequences of Figure 13. Accordingly, Applicants do not believe a new sequence listing is required. However, the specification has been amended to refer to SEQ ID NOS. 11-14 in the Brief Description of the Drawings. Applicants believe this amendment is fully responsive to the Examiner's objections.

REJECTIONS UNDER 35 U.S.C. § 112, FIRST PARAGRAPH

Claims 38-44, 46 and 47 stand rejected under 35 U.S.C. § 112, first paragraph due to the phrase "as illustrated in Figure 12". This phrase has been deleted from claims 38 and 39, upon which the remaining claims depend. Accordingly, these rejections are moot.

REJECTIONS UNDER 35 U.S.C. § 103(a)

Claims 38-44, 46 and 47 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Schlom et al. (U.S. Pat. No. 6,045,802) in view of Matteuci (U.S. Pat. No. 4,923,808), Horig (Cancer Immunol. Immunother., 49: 504-514 (2000), and Parmiani et al. (J. Natl. Cancer Inst., 94: 805-818 (2002). Applicants respectfully disagree with these rejections, as set forth below.

The rejection alleged that Schlom teaches the use of CEA (but not Applicants' SEQ ID NO.: 6) and B7 in a cancer vaccine and that Matteucci teaches the use of silent mutations to beneficially affect protein translation. The rejection alleged that "[a]ll of the component parts are taught by Schlom et al. and Matteucci", the "only difference" between the claimed subject matter and what is taught by Schlom and Matteucci being "the combination of 'old elements' into a single expression system comprising SEQ ID NO. 6 and a nucleic acid sequence encoding human B7.1." The rejection concludes that it would have been obvious "to make silent mutations" in the wild-type CEA sequence "because Matteucci teaches that making silent mutations in a nucleic acid sequence increases the translation of the protein." This line of reasoning simply cannot support a proper *prima facie* case of obviousness.

Applicants respectfully disagree that "[a]ll of the component parts" are found in Schlom and Matteucci. The "parts" of the claimed subject matter include an expression vector, a nucleotide sequence encoding a human CEA polypeptide and containing 246 specific mutations to the "wild-type" CEA nucleotide sequence (e.g., Fig. 9), and a nucleotide sequence encoding human B7.1. While certain expression vectors, wild-type CEA, and human B7.1 may be in the prior art, the rejection acknowledges that SEQ ID NO.: 6 is not found in Schlom. In fact, none of the mutations to wild-type CEA shown in SEQ ID NO.: 6 are found in Schlom. Matteucii does not disclose any CEA-encoding nucleotide sequences. Matteucci generally describes methods for introducing silent mutations into nucleic acids. However, as set forth in PharmaStem Therapeutics v. ViaCell, Inc.:

> ". . . an invention would not be deemed obvious if all that was suggested 'was to explore a new technology or general approach that seemed to be a promising field of experimentation, where the prior art gave only general guidance as to the particular form of the claimed invention or how to achieve it.'" 491 F.3d 1342, 1364 (Fed. Cir., 2007), *citing* In re O'Farrell, 853 F.2d 894, 903 (Fed. Cir. 1988)

The pending rejections are completely contrary to Pharmastem. Matteucci provides, at most, general guidance as to how to modify nucleic acid sequences, and a limited number of specific examples of modified nucleic acid sequences. Matteucci does

not provide any guidance as to the "particular form of the claimed invention or how to achieve it" (e.g., SEQ ID NO.:6). Matteucci provides no guidance whatsoever regarding which particular nucleotides should be modified to eliminate the problems related to expressing recombinant CEA. Applicants were the first to recognize a solution to the problems associated with expressing recombinant CEA, which is represented by SEQ ID NO.: 6. Neither Schlom nor Matteucci suggest modifying wild-type CEA (e.g., SEQ ID NO.: 1) in *any* way, much less in the *particular* way shown in SEQ ID NO.: 6.

The rejection does not present a legally sufficient *prima facie* showing of obviousness regarding SEQ ID NO.: 6, a key feature of the claimed subject matter. The rejections of independent claims 38 and 46, and the dependent claims thereof, are improper. Neither Horig nor Parmiani cure the deficiencies in the combination of Schlom and Matteucci. As such, Applicants respectfully request withdrawal of these rejections.

CONCLUSIONS

Reconsideration of this application, as amended, is respectfully requested. A Notice of Allowance for all claims is also respectfully requested. The Examiner is encouraged to contact the undersigned if it is believed doing so would expedite prosecution.

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